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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10777.572
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	First Named Inventor	BURTON
	Art Unit	3743
	Examiner Name	ALI, S.B.
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ENCLOSURES (Check all that apply)		
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	FULBRIGHT & JAWORSKI LLP		
Signature	<i>John F. Klos</i>		
Printed name	John F. Klos		
Date	May 14, 2007	Reg. No.	37,162

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Docket No.: 24,577-45CIP
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
BURTON, D.

Application No.: 10/777,572

Art Unit: 3743

Filed: Feb. 11, 2004

Examiner: ALL, S.B.

For: BIO-MASK WITH INTEGRAL SENSORS

APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-01450

Dear Sir:

As required under 37 CFR §1.192, this Appeal Brief was filed within two months from the date of the Notice of Appeal, March 13, 2007, and is in furtherance of said Notice of Appeal.

I. Real Party in Interest

The real party in interest is the sole assignee of the present application, Compumedics Limited.

II. Related Appeals and Interferences

There are no related appeals or interferences which would directly effect or be directed effected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1 - 31 are pending, stand rejected, and are appealed herein. A copy of the pending claims is attached.

IV. Status of Amendments

An amendment filed September 4, 2006, was entered. No subsequent amendment has been made.

V. Summary of Claimed Subject Matter

A brief summary of the invention is followed by a concise explanation of the subject matter defined in each independent claim involved in the appeal, including reference to the specification by page and line number and to the drawings by reference numbers.

The present invention is directed to a gas mask assembly and method of use incorporating physiologic sensors, e.g., EEG sensors, for acquiring information relating to a patient / user of the mask. In some embodiments, the mask assembly includes a processor and controlled gas source for varying an amount of gas delivered to the mask as a function of acquired physiologic conditions of the mask user.

A concise explanation of the subject matter defined in each independent claim involved in the appeal follows, including reference to the specification by page and line number and to the drawings by reference numbers.

Claim 1: The subject matter of this claim involves a mask assembly having a body defined by an internal surface, an external surface, and a perimeter surface, and a forehead support connected to the body. FIGS. 8-12, p. 13, lines 1-5. The forehead support has an EEG sensor located thereon. P. 5, lines 6-11.

Claim 8: The subject matter of claim 8 is directed to a gas delivery system incorporating a mask having at least one physiological sensor connected thereto, a gas delivery device having an adjustable gas delivery setting, and a processor in communication with the gas delivery device and the sensor. P. 18, lines 12-17. The processor is adapted to determine the existence of a sleep disorder and to adjust the gas delivery setting based on the determination. P. 18, lines 8 – 11.

Claim 14: The subject matter of claim 14 is directed a gas delivery system incorporating a mask having at least one EEG sensor connected thereto, a gas delivery device having an adjustable gas delivery setting and a processor in communication with the gas delivery device and the EEG sensor. P. 18, lines 12-17. The processor is adapted to determine arousal and to adjust the gas delivery setting based thereon.

Claim 17: The subject matter of claim 17 is directed a method of providing a mask adapted to detect physiological signals and to deliver a gas, providing a gas delivery device in fluid communication with the mask and having an adjustable gas output, determining a sleep state from physiological signals detected by the mask, and adjusting the output from the gas delivery device based on the sleep state. P. 18, lines 5-11.

Claim 21: The subject matter of claim 21 is directed a method of obtaining SPO₂ reading from a mask comprising: attaching a light source and a light sensor on a mask so that the light source and light sensor are positioned to contact a person's forehead, illuminating the light source, detecting light from the light source as it deflects from the person's skull and converting the detected light into an analog signal. P. 17 lines 20-23, P. 19, lines 1-4.

Claim 22: The subject matter of claim 22 is directed a method detecting oral or nasal breathing during nasal ventilation, comprising: providing a mask adapted to form a seal between a patient's nose and mouth, the mask having an interior surface and an exterior surface, the mask also having a first thermal sensor on the interior surface and a second thermal sensor located on the exterior surface to be adjacent the patient's mouth and detecting a temperature change in the first or second thermal sensor. FIG. 11, 12, P.13, lines 12-21; FIG. 6, P. 8, line 23 and P. 9, lines 1-9; FIG. 7 lines 6-16.

Claim 23: The subject matter of claim 23 is directed an apparatus incorporating a mask having a body position sensor attached thereto and a processor in communication with the sensor and adapted to a determine body position from the body position sensor's output. FIGS. 6 and 7, P. 11, lines 5-9.

Claim 25: The subject matter of claim 25 is directed a method of detecting a leak in a breathing mask including providing a mask having a perimeter surface with a plurality of thermally conductive surfaces distributed throughout the perimeter surface; and detecting a temperature change in any of the plurality of thermally conductive surfaces. FIG. 11, 12, P.13, lines 12-21; FIG. 6, P. 8, line 23 and P. 9, lines 1-9; FIG. 7 lines 6-16.

Claim 26: The subject matter of claim 26 is directed an apparatus incorporating a body having an internal surface, an external surface, and a perimeter surface and a forehead support extending from the body and adapted to contact a forehead surface of a patient during use. The forehead support has a plurality of sensors located thereon for detecting electrophysiological signals of the patient. FIGS. 8-12, p. 13, lines 1-5, P. 5, lines 6-11.

Claim 30: The subject matter of claim 30 is directed a gas delivery system incorporating a gas mask adapted to fit on a patient; a gas delivery device having an adjustable gas delivery; and a processor in communication with the gas delivery device and a cardiac pacemaker. The processor is adapted to adjust the gas delivery based on a signal from the cardiac pacemaker. FIGS. 6 and 7, P. 4, lines 7-12.

VI. Grounds of Rejection to be Reviewed on Appeal

1. Are claims 1, 4-26, 28-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US Pat. No. 5,353,788 ("Miles '788")?

2. Are claims 1, 3 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles '788 in view of Kwok US Patent No. 6,532,961 ("Kwok '961")?

VII. Argument**A. Grouping of Claims:**

- a. Regarding the §103(a) rejection based on Miles '788, claims 1, 4-7 and 21 stand together.
- b. Regarding the §103(a) rejection based on Miles '788, claims 8-13 stand together.
- c. Regarding the §103(a) rejection based on Miles '788, claims 14-20 stand together.
- d. Regarding the §103(a) rejection based on Miles '788, claim 22 stands alone.
- e. Regarding the §103(a) rejection based on Miles '788, claims 23-24 stand together.
- f. Regarding the §103(a) rejection based on Miles '788, claim 28 -29 stand together.
- g. Regarding the §103(a) rejection based on Miles '788, claims 30-31 stand together.
- h. Regarding the §103(a) rejection based on Miles '788 and Kwok '971, claims 1, 3 and 27 stand together.

B. Standard of Review

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act, 5 U.S.C. §706(A), (E), 1994. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). Moreover, the Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). In *In re Gartside*, the Federal Circuit stated that "the 'substantial evidence' standard asks whether a reasonable fact finder could have arrived at the agency's decision." *Id.* at 1312.

Accordingly, the Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences.

C. Application to Claims

i. *Claims 1, 4-26, 28-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Miles '788*

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art cited must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Claim 1: Claim 1 requires an EEG sensor located on a forehead support. The Office Action admits that *Miles* does not disclose the forehead support having an EEG sensor located thereon. The Office Action attempts to cure this deficiency by suggesting that the location of the EEG sensor is not critical. It is submitted that the location of an EEG sensor is critical and that it would not have been obvious to locate an EEG sensor on the mask assembly of *Miles*. The prior art teaches cap-based EEG sensors, such as disclosed in US Pat. 5,293,867, wherein the positioning of individual sensors is carefully predetermined in order to acquire meaningful EEG signals. As *Miles* does not teach or suggest at least this feature of claim 1, Applicant respectfully asserts that claim 1 is patentable over the 35 U.S.C. § 103 rejection of record.

It is well settled that the fact that references can be combined or modified is not sufficient to establish a prima facie case of obviousness, M.P.E.P. § 2143.01. The cited motivation is merely a statement that *Miles* can be modified, and does not state any desirability for making the modification. The mere fact that *Miles* can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990), as cited in M.P.E.P. § 2143.01. Thus, the motivation provided by the Examiner is improper, as the motivation must establish the desirability for making the modification. As no valid suggestion has been made as to why placing an EEG on a forehead support of *Miles* is desirable, the rejection of claim 1 should be

withdrawn.

Claim 4: Claim 4 requires an SP02 sensor located on a forehead support bar. The Office Action suggests that it would have been obvious to one of ordinary skill in the art to place such a sensor in a forehead support bar in view of *Miles*. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. *Miles* does not teach a forehead support bar nor does it teach positioning an SP02 sensor on the forehead support bar. As *Miles* does not teach or suggest at least these two features of claim 4, Applicant respectfully asserts that claim 4 is patentable over the 35 U.S.C. § 103 rejection of record.

Claim 5. Claim 5 requires an EEG sensor including a pad of conductive carbonized rubber material. The Office Action makes no mention of such structure. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach an EEG sensor having a conductive rubber material, Applicant respectfully asserts that claim 5 is patentable over the 35 U.S.C. § 103 rejection of record.

Claim 6. Claim 6 requires an sensor located on a strap extending from the mask. The Office Action suggests that it would have been obvious to one of ordinary skill in the art to place such a sensor in a strap in view of *Miles*. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. *Miles* does not teach positioning a sensor on a strap. As *Miles* does not teach or suggest at least this feature of claim 6, Applicant respectfully asserts that claim 6 is patentable over the 35 U.S.C. § 103 rejection of record.

Claim 7: For the reasons relating to claims 1 and 5 above, it is submitted that *Miles* does not teach a conductive material adapted to measure an EOG.

Claims 8 - 13: Claim 8 requires a processor adapted to determine the existence of a sleep disorder and to adjust the gas delivery setting based on such determination. The Office Action suggests that *Miles* teaches such a processor for determining the existence of a sleep order simply referring to Figure 2 of *Miles*. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. *Miles* does not teach a processor for determining the existence of a sleep disorder or adjusting a gas delivery setting based on such a determination. Applicant respectfully asserts that claims 8-13 are patentable over the 35 U.S.C.

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-7-

§ 103 rejection of record.

Claims 14 - 16: Claim 14 requires a processor adapted to determine the state of arousal and to adjust the gas delivery setting based on such determination. The Office Action makes no reference to *Miles* as teaching a processor for determining the state of arousal of a subject. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. *Miles* does not teach a processor for determining the state of arousal or adjusting a gas delivery setting based on such a determination. Applicant respectfully asserts that claims 14-16 are patentable over the 35 U.S.C. § 103 rejection of record.

Claims 17-20: Claim 17 requires determining a sleep state of a subject and adjusting output of a gas delivery device based on the determined sleep state. The Office Action suggests that *Miles* discloses structures that can be used to perform steps cited in claims 17-20. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. *Miles* does not teach the structure of a processor for determining subject sleep state, and there exists no structure in *Miles* capable of performing the steps of determining subject sleep state. Applicant respectfully asserts that claims 17-20 are patentable over the 35 U.S.C. § 103 rejection of record.

Claims 21, 22: Claim 21 requires the method of attaching a light source at the mask and a light sensor positioned to contact the subject's forehead. The Office Action suggests that *Miles* discloses structures that can be used to perform steps cited in claims 21, 22. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. *Miles* does not teach the structure of mask with a light source and a light sensor positioned at the subject's forehead. Applicant respectfully asserts that claims 21, 22 are patentable over the 35 U.S.C. § 103 rejection of record.

Claim 22: Claim 22 requires a mask with a first thermal sensor positioned on an interior mask surface and a second thermal sensor positioned on an exterior mask surface. The Office Action makes no reference to *Miles* as teaching a pair of separately positioned thermal sensors. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach these limitations, Applicant respectfully asserts that claim 22 is patentable over the 35 U.S.C. § 103 rejection of record.

Claim 23, 24: Claim 23 requires a mask having a body position sensor attached thereto. The Office Action makes no reference to *Miles* as teaching a body sensor attached to the mask. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach these limitations, Applicant respectfully asserts that claims 23, 24 are patentable over the 35 U.S.C. § 103 rejection of record.

Claim 25: Claim 25 requires a mask having a plurality of thermally conductive surfaces distributed throughout a perimeter surface. The Office Action makes no reference to *Miles* as teaching mask having a plurality of thermally conductive surfaces at a mask perimeter. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach these limitations, Applicant respectfully asserts that claim 25 is patentable over the 35 U.S.C. § 103 rejection of record.

Claim 23: Claim 23 requires a mask having a body position sensor attached thereto. The Office Action makes no reference to *Miles* as teaching a body position sensor attached to the mask. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach these limitations, Applicant respectfully asserts that claim 23 is patentable over the 35 U.S.C. § 103 rejection of record.

Claims 26-29: The arguments of claim 1 apply to claims 26-29, i.e., *Miles* does not disclose a forehead support having a sensor located thereon.

Claim 29: As *Miles* does not teach the limitation of a mask seal leakage detector, Applicant respectfully asserts that claim 29 is patentable over the 35 U.S.C. § 103 rejection of record.

Claims 30-31: Claim 30 requires a processor in communication with a cardiac pacemaker adapted to adjust gas delivery to the subject based on a signal from the pacemaker. The Office Action makes no reference to *Miles* as teaching a pacemaker. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach this limitation, Applicant respectfully asserts that claims 30-31 are patentable over the 35 U.S.C. § 103 rejection of record.

Claim 31: Claim 31 requires a processor adapted to determine the existence of a sleep

disorder of a subject. The Office Action makes no reference to *Miles* as teaching a processor for determining a sleep disorder of the subject. To establish a prima facie case of obviousness, the prior art cited must teach or suggest all the claim limitations. As *Miles* does not teach a processor for determining a sleep disorder, Applicant respectfully asserts that claim 31 is patentable over the 35 U.S.C. § 103 rejection of record.

ii. Claims 2, 3 and 27 are rejected under 35 U.S.C 103(a) as being unpatentable over Miles '788 in view of Kwok '961

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art cited must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

Claim 2: Claim 2 requires a thermosensitive coating at a perimeter surface of a mask. Since neither Kwok nor *Miles* disclose a thermosensitive coating at a mask perimeter, Applicant respectfully asserts that claim 2 is patentable over the 35 U.S.C. § 103 rejection of record.


Claim 3: As a dependent claim of claim 1, the arguments of claim 1 apply to claim 3. Applicant respectfully asserts that claim 3 is patentable over the 35 U.S.C. § 103 rejection of record.

Claim 27: As a dependent claim of claim 26, the arguments of claim 26 apply to claim 27. Applicant respectfully asserts that claim 26 is patentable over the 35 U.S.C. § 103 rejection of record.

In light of the foregoing, appellant respectfully submits that all pending claims are patentable. Therefore, it is respectfully requested that the Board reverse each of the pending rejections.

Any filing fees associated with this Appeal Brief may be charged to the Deposit Account of the Undersigned, Dep. Acct. #50-1212 (ref. 10310190).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John F. Klos". The signature is stylized with a large, sweeping initial "J" and "K".

John F. Klos
Reg. No. 37,162

Fulbright & Jaworski L.L.P.
80 South Eighth Street
Minneapolis, MN 55402
612-321-2806

Date: May 14, 2007

CLAIMS APPENDIX:

1. (Original) A mask assembly comprising:
 - a body having an internal surface, an external surface, and a perimeter surface; and
 - a forehead support connected to the body, the forehead support having an EEG sensor located thereon.
2. (Original) The assembly of claim 1, wherein the perimeter surface includes a padding material having a thermosensitive coating.
3. (Previously Presented) The assembly of claim 1 wherein the forehead support includes a forehead support bar extending in a generally lateral direction from the forehead support.
4. (Original) The assembly of claim 3, and wherein an SPO2 sensor is located on the forehead support bar.
5. (Original) The assembly of claim 4, wherein the EEG sensor includes a pad comprised of a conductive carbonized rubber material.
6. (Original) The assembly of claim 1, and further comprising a strap extending from the mask, and wherein a physiological sensor is located on the strap.
7. (Previously Presented) The assembly of claim 5, wherein a portion of the conductive material is adapted to measure EOG.
8. (Original) A gas delivery system comprising:
 - a mask having at least one physiological sensor connected thereto;
 - a gas delivery device having an adjustable gas delivery setting; and
 - a processor in communication with the gas delivery device and the sensor, the processor adapted to determine the existence of a sleep disorder and to adjust the gas delivery setting based thereon.

9. (Original) The system of claim 8, wherein the sensor is an EMG sensor.
10. (Original) The system of claim 8, wherein the sensor is an ECG sensor.
11. (Original) The system of claim 10, and further comprising a SPO2 sensor connected to the mask.
12. (Original) The system of claim 8, wherein the sensor is an EEG sensor.
13. (Original) The system of claim 8, wherein the processor is also adapted to determine patient arousal.
14. (Original) A gas delivery system comprising:
a mask having at least one EEG sensor connected thereto;
a gas delivery device having an adjustable gas delivery setting; and
a processor in communication with the gas delivery device and the EEG sensor, the processor adapted to determine arousal and to adjust the gas delivery setting based thereon.
15. (Original) The system of claim 14, wherein an SPO2 sensor and an ECG sensor are connected to the mask, and wherein the processor is in communication with both sensors and is adapted to derive a PTT value from an output of each sensor.
16. (Original) The system of claim 14, and further comprising a strap extending from the mask and a plurality of EMG sensors located on the mask and strap, the EMG sensors positioned to detect muscle activity related to sleep state.
17. (Original) A method of delivering gas comprising:
providing a mask adapted to detect physiological signals and to deliver a gas;
providing a gas delivery device in fluid communication with the mask and having an adjustable gas output;
determining a sleep state from physiological signals detected by the mask; and

adjusting the output from the gas delivery device based on the sleep state.

18. (Original) The method of claim 17, wherein determining a sleep state includes determining arousal.

19. (Original) The method of claim 18, wherein determining arousal includes calculating PTT values from an SPO2 and ECG readings.

20. (Original) The method of claim 18, wherein determining arousal includes analyzing cortical and subcortical EEG signals.

21. (Original) A method of obtaining SPO2 reading from a mask comprising:
attaching a light source and a light sensor on a mask so that the light source and light sensor are positioned to contact a person's forehead;
illuminating the light source;
detecting light from the light source as it deflects from the person's skull; and
converting the detected light into an analog signal.

22. (CANCELED) The method of claim 21, and further comprising the additional step of high pass filtering the analog signal.

22. (Original) A method of detecting oral or nasal breathing during nasal ventilation, the method comprising:

providing a mask adapted to form a seal between a patient's nose and mouth, the mask having an interior surface and an exterior surface, the mask also having a first thermal sensor on the interior surface and a second thermal sensor located on the exterior surface to be adjacent the patient's mouth;

detecting a temperature change in the first or second thermal sensor.

23. (Original) An apparatus comprising:
a mask having a body position sensor attached thereto;

a processor in communication with the sensor and adapted to determine body position from the body position sensor's output.

24. (Original) The apparatus of claim 23, and further comprising movement sensor attached to the mask and in communication with the processor, and wherein the processor is also adapted to determine movement from an output of the movement sensor.

25. (Original) A method of detecting a leak in a breathing mask:

providing a mask having a perimeter surface with a plurality of thermally conductive surfaces distributed throughout the perimeter surface; and
detecting a temperature change in any of the plurality of thermally conductive surfaces.

26. (Original) A mask assembly comprising:

a body having an internal surface, an external surface, and a perimeter surface; and
a forehead support extending from the body and adapted to contact a forehead surface of a patient during use, the forehead support having a plurality of sensors located thereon for detecting electrophysiological signals of the patient.

27. (Original) The mask assembly of claim 26 wherein the forehead support includes a support pad in contact with the forehead surface.

28. (Original) The mask assembly of claim 26 further comprising:

a movement sensor for detecting movement of the patient during use.

29. (Original) The mask assembly of claim 26 further comprising:

a mask seal leakage detector.

30. (Original) A gas delivery system comprising:

a gas mask adapted to fit on a patient;
a gas delivery device having an adjustable gas delivery; and
a processor in communication with the gas delivery device and a cardiac pacemaker, the

processor adapted to adjust the gas delivery based on a signal from the cardiac pacemaker.

31. (Original) The gas delivery system of claim 30 wherein the processor receives an additional electrophysiological signal from the patient, and said processor determines the existence of a sleep disorder based upon the signals.

EVIDENCE APPENDIX:

Copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or any other evidence entered by the examiner and relied upon by appellant in the appeal:

NONE

RELATED PROCEEDINGS APPENDIX:

Decisions rendered by a court of the Board in the proceeding identified in the Related Appeals
and Interferences section of the brief:

NONE